

AMENDMENTS TO THE CLAIMS

Claims 1-10 (Cancelled)

Kindly add the following new claims:

11. (New) A pharmaceutical composition which can be administered orally, allowing the controlled release of at least one active substance, comprising:

- a) said at least one active substance,
- b) between 5% and 60% by weight, relative to the total weight of the composition, of at least one excipient, selected from the group consisting of inert matrices, hydrophilic matrices, lipid matrices, mixtures of inert matrices and of lipid matrices, mixtures of hydrophilic matrices and of inert matrices,
with the exception of mixtures comprising a polyacrylic acid and at least one hydrophilic cellulose matrix;
- c) between 9% and 14.3% by weight, relative to the total weight of the composition, of at least one alkalizing agent soluble in an aqueous phase under physiological pH conditions, selected from alkali or alkaline-earth metal hydroxides, carbonates, bicarbonates, phosphates, sodium borate and basic salts of organic acids.

12. (New) The pharmaceutical composition according to claim 11, wherein said at least one active substance is selected from the group consisting of pseudoephedrine, efletirizine, trapidil, hydrocodone, cetirizine, their optical isomers and their pharmaceutically acceptable salts.

13. (New) The pharmaceutical composition according to claim 11, wherein said matrix excipient is hydroxypropyl methylcellulose.

14. (New) The pharmaceutical composition according to claim 11, further comprising one or more additional pharmaceutically acceptable excipients.

15. (New) The pharmaceutical composition according to claim 14, wherein said one or more additional pharmaceutically acceptable excipients is selected from the group consisting of diluents, binders, disintegrants, lubricants, taste-masking agents, flavorings, colorings and coating agents.

16. (New) A process for preparing a pharmaceutical composition according to claim 11, which comprises the following successive steps:

- (i) preparing a homogeneous mixture containing components a), b) and c) according to claim 11 and additional excipients optionally present; and
- (ii) tableting the homogeneous mixture obtained in step (i), optionally after granulation.

17. (New) A pharmaceutical composition which can be administered orally, allowing the immediate release of a first active substance and the prolonged release of the same first active substance or of a second active substance, comprising

A. at least one layer comprising said first active substance and excipients which allow the immediate release of said first active substance after administration, and

B. at least one second layer which allows the prolonged release of the same said first active substance or of a second active substance,

wherein said at least one second layer is a pharmaceutical composition according to claim 11.

18. (New) The pharmaceutical composition according to claim 17, wherein the immediate-release layer A is in contact with the prolonged-release layer B.

19. (New) A process for the preparation of a pharmaceutical composition according to claim 17, which comprises the following successive steps:

(1) preparing separate homogeneous mixtures of components forming layers A and B respectively, and

(2) tabletting said mixtures obtained in step (1) in a multilayer tabletting machine.

20. (New) The process for preparation according to claim 19, wherein the tabletting step (2) is preceded by a step of granulating said homogeneous mixtures obtained in step (1).

21. (New) The pharmaceutical composition according to claim 11, wherein said matrix excipient is present in a total amount from 15.4% to 54% by weight, relative to the total weight of the composition.

22. (New) The pharmaceutical composition according to claim 11, wherein said alkalizing agent is an alkali metal carbonate.

23. (New) The pharmaceutical composition according to claim 22, wherein said alkalizing agent is Na₂CO₃.

24. (New) The pharmaceutical composition according to claim 11, wherein the controlled release formulation is in the form of a single unit, single dose formulation.

25. (New) The pharmaceutical composition according to claim 11, wherein said at least one active substance is cetirizine, an optical isomer or pharmaceutically acceptable salt thereof.